## FOLEY LARDNER

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**FOLEY & LARDNER** 

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CLIENT/MATTER NUMBER 080618-0209

## VIA ELECTRONIC MAIL AND U.S. MAIL

Division of Dockets Management Food and Drug Administration 5630 Fishers Lane rm. 1061 Rockville, MD 20852 COPY COPY

Re:

Docket No. 2003E-0245

Determination of Regulatory Review Period for Purposes of Patent

Extension: REMODULIN

Dear Sir:

These Comments are submitted on behalf of the Applicants (United Therapeutics, Corp.) for Patent Term Extension of Remodulin in response to the January 29, 2004 Federal Register Notice requesting comments and petitions of the Patent Term Extension.

The Notice states, on page 4, numbered paragraph 3, that "[i]n its application for patent extension, this applicants seeks 337 days of patent term extension." Contrary to this statement in the Notice, Applicants seek 4 years and 333 days in their application for Patent Term Extension filed July 8, 2002.

Applicants of the Patent Term Extension application for Remodulin request that the FDA publish an errata stating the correct amount of patent term extension that Applicants seek in their application.

Very truly yours,

Stephen B. Maebius

SBM/MCC